510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K052598

B. Purpose for Submission:

Marketing in the US

C. Measurand:

Human Hemoglobin

D. Type of Test:
Immunological test for the qualitative detection of monoclonal antibodies for human hemoglobin

E. Applicant:

Care Diagnostic, Inc.

F. Proprietary and Established Names:

ImmoCARE Fecal Occult Blood (FOB) Test

G. Regulatory Information:

1. Regulation section:

   21 CFR § 866.6550

2. Classification:

   Class II

3. Product code:

   KHE, Reagent, Occult Blood

4. Panel:

   Hematology 81

H. Intended Use:

1. Intended use(s):

   The ImmoCARE® test is a rapid, immunochromatographic assay for the qualitative detection of intact hHb (human hemogloboin) in fecal specimens. It is a convenient and hygienic method for detecting human fecal occult blood, which may be indicative of gastrointestinal diseases associated with bleeding such as colorectal carcinoma, Crohn's disease, ulcerative colitis, and colon polyps in humans.

2. Indication(s) for use:

   ImmoCARE® is an immunological test for both professional and home-use.

3. Special conditions for use statement(s):

   N/A

4. Special instrument requirements:

   N/A

I. Device Description:

The ImmoCARE FOB test kit consists of sampling bottles containing an extraction buffer and the immunochromatographic test in cassettes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ColonCARE

   Hemoccult guaiac test

2. Predicate 510(k) number(s):

   K030216

   K880499

3. Comparison with predicate:

Similarities			
Item	Device	Predicate K030216	Predicate K880499
Test Principle	Immunoassay utilizing MAbs for the detection of human hemoglobin	Immunoassay utilizing MAbs for the detection of human hemoglobin	
Sample	Feces in extraction buffer	Feces in extraction buffer	

Differences			
Item	Device	Predicate K030216	Predicate K880499
Test Principle	Immunoassay utilizing MAbs for the detection of human hemoglobin		Guaiac test
Sample	Feces in extraction buffer		Feces on slide card

K. Standard/Guidance Document Referenced (if applicable):

"Review Criteria for the Qualitative Assessment of Fecal Occult Blood In Vitro Diagnostic Devices"

L. Test Principle:

After application of the sample to the sample well, the sample (and if present, the hHb) migrates to a membrane coated with colloidal-antibody-gold-conjugates by capillary action. If hHb is present, it binds to the its binding partner, the anti-β-hHb monoclonal antibody-colloidal gold conjugate, forming a colored complex. The complex continues migrating to a line of immobilized anti-hHb antibody coated onto the results field in the form of a line (labeled "T" (Test line) on the cassette). As a result, a pink-rose color-line appears in the results field at the position of the "T", if hHb is present.

As an internal quality control, the normal rabbit IgG colloidal-antibody-gold-conjugate coated in the membrane start migrating as well. This IgG colloidal antibody-gold conjugate will be captured in the results field via goat anti-(rabbit IgG) polyclonal antibody at the position labeled with "C" (Control Line) on the cassette

forming a pink-rose Control Line independent of the whether hHb is present or not and therefore serves as a control for the correct testing procedure.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility studies were conducted using human hemoglobin free stool extracts from 6 subjects. Samples were collected and separated in five groups of six for a total of 30 samples. Each group of specimens was spiked with a known level of human hemoglobin to result in the following concentrations; 0 mg/l, 1,370 mg/l, 137 mg/l, 13.7 mg/l and 1.37 mg/l. The results of the studies are presented in the table below.

Reproducibility studies for ImmoCARE

	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6
0 mg/l	-	-	-	-	-	-
1370 mg/l	+++	+++	+++	+++	+++	+++
137 mg/l	++	++	++	++	++	++
13.7 mg/l	-	-	-	-	-	-
1.37 mg/l	-	-	-	-	-	-

b. Linearity/assay reportable range:

N/A

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Internal Control: Is built into the test strip and assures that the sample addition and migration through the test strip has occurred and that the control anti-mouse antibody and the reporter antibody are intact and functional.
External Control: Assures that the capture and conjugated antibodies are present and reactive. Positive and negative controls are available from CARE Diagnostics, Inc.

d. Detection limit:

The minimal detectable concentration of hHb is 0.05 µg/ml in buffer or 0.03 mg hHb/g stool.

e. Analytical specificity:

Animal hemoglobins and tissues

A performance study was completed to investigate the cross reactivity of other species of hemoglobin (Hb) and tissue extracts on the ImmoCARE FOB test. Hb of bovine, equine, pig, rabbit, sheep, chicken and origin was added to the

test device to determine the cross reactivity of the test with Hb of other species. The results continued to be negative after the addition of each Hb species.

Dietary substances

A performance study was completed to investigate the interference of dietary substances on the ImmoCARE FOB test. Raw cantaloupe, radish, horseradish, broccoli, cauliflower, parsnip, paprika, parsley, leak and turnip were added to the test device to determine if vegetable extracts cross react with the test. The extracts were prepared by homogenizing raw vegetable in a food processor. Dietary iron and Vitamin C supplements and were also tested for cross reactivity. The dietary substance extracts were added to normal stool extracts. The results continued to be negative after the addition of each dietary substance.

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Studies were performed comparing five different guaiac FOB tests, including the Hemoccult test. All of the examined FOB tests performed similarily.

b. Matrix comparison:

N/A

3. Clinical studies:

A clinical study was performed at a gastroenterology center on 253 patients (131 females and 122 males) between the ages of 19-88 years. The results of the predicate (Hemoccult guaiac test) and the ImmoCARE tests were compared to reference test (colonoscopy) results. The comparison is shown below:

	Colonoscopy	**ImmoCARE**	**Hemoccult**
Normal	158	186 Neg	222 Neg
Results with Pathological findings	95	67 Pos	31 Pos
Total	253	253	253

a. Clinical Sensitivity:

The clinical sensitivity is 62.1% compared to Hemoccult's 29.4% when compared to colonoscopy.

b. Clinical specificity:

The clinical specificity is 95% compared to Hemoccult's 98% when compared to colonoscopy.

c. Other clinical supportive data (when a. and b. are not applicable):
A study on the interpretation of lay readers (N=83) from various educational backgrounds and over the age of 50 y.o. was also performed. When compared to expert readings, lay readers had agreement rates of 97.43% for positive tests, 95.6% for negative tests and 100% for invalid tests.

4. Clinical cut-off:

The cut-off was determined to be 0.03 mg hHb/g stool.

5. Expected values/Reference range:

Negative < 0.03 mg/hHb/g stool

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.